REMARKS

Applicant respectfully requests reconsideration of the application in view of the following remarks.

I. Status of the Claims

Claims 24-26 are added to recite specific embodiments, described, for example, at page 8 of the specification as filed. Upon entry of these amendments, claims 1-26 will be pending. These claims are presented for reconsideration.

II. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The specific grounds of rejection are addressed below.

A. "Below Processing Temperatures"

The Office Action rejects claim 1 as allegedly indefinite for reciting "below processing temperatures." Office Action, page 2. Specifically, the Office Action states that "the phrase renders the claim unclear because this processing temperature is not recited." Applicant respectfully traverses this rejection.

As explained in the previous response filed June 29, 2007, the proper inquiry in assessing compliance with 35 U.S.C. § 112, second paragraph, is "whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity." MPEP § 2173.02 (emphasis added). The claim language must not be considered in a vacuum. *Id.* Instead, the teachings of the prior art and the understanding of the skilled artisan must also be considered. *Id.*

Here, the claims define the claimed subject matter with a reasonable degree of clarity and particularity, and one of skill in the art would readily understand the metes and bounds of the recited "processing temperatures." As indicated in the specification, the "processing temperatures" are those at which the transdermal compositions are processed. *See* Specification, paragraph bridging pages 10-11. Persons skilled in the art will recognize the

processing temperatures being used for a given transdermal system and, therefore, can readily determine whether a given system is substantially free of liquids having a boiling point below such processing temperatures. Thus, the claims do not need to recite specific processing temperatures in order to satisfy §112.

Reciting specific processing temperatures as the Office Action would require would unduly restrict the scope of protection for Applicant's invention. Because one skilled in the art would readily recognize whether a given transdermal system meets the claimed limitation of "below processing temperatures," there is no legitimate reason to require the claims to be narrowed.

Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

B. "Equal To Or Greater Than The Normal Boiling Points Of The At Least One Low Molecule Weight Drug"

The Office Action rejects claims 1 and 5 for reciting "equal to or greater than the normal boiling points of the at least one low molecule weight drug." According to the Office Action, "[t]he meaning is vague since the drug is not known; there is no way to compare its boiling point." Office Action at page 3. Applicant respectfully traverses this rejection.

The claims are clear and definite as written. The skilled artisan readily will understand the metes and bounds of the recitation that the transdermal system be substantially free of water and liquids having a boiling point equal to or greater than the normal boiling points of the at least one low molecular weight drug. For example, when formulating a transdermal system, the skilled artisan may select one or more low molecular weight drugs, at which point he or she will know (or readily could determine) the normal boiling point of the selected low molecular weight drug(s), and thus will know (or readily could determine) whether the transdermal system is substantially free of liquids having a boiling point equal to or greater than the normal boiling points of the selected low molecular weight drug(s). Thus, the claims do not need to recite specific drugs or their normal boiling points in order to satisfy §112.

Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

III. Claim Rejections – 35 U.S.C. § 102

A. WO 93/00058 to Miranda *et al.*

Claims 1-6 and 10-21 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by WO 93/00058 to Miranda *et al* ("Miranda"). According to the Office Action, regarding the claimed "shear resistance" property, "[b]ecause the same compounds have the same properties, the new amendments to the claims which recite "pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" [i]s an inherent property to the same compounds of the preparation disclosed by Miranda" Office Action at page 4. Applicant respectfully traverses this rejection.

As explained in the previous response, Miranda does not anticipate the claimed invention because, for example, Miranda does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer and (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug and liquid at or about room temperatures, as set forth in claim 1. Indeed, the Office Action fails to identify any particular polymer described by Miranda that is a "high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" or having a shear resistance "which is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit," let alone a teaching to use such a polymer in a transdermal system with a low molecular weight drug, as required by claims 1-6 and 10-21.

While the Office Action asserts that Miranda inherently teaches the "high shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit," the Office Action does not explain with sufficient rationale how Miranda inherently provides this teaching, as required for a rejection based on inherency.

MPEP 2112 explains the requirements for an inherency rejection:

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

In the present case, the Office Action merely asserts that "the same compounds have the same properties" (page 4), but does not provide the explanation required, or identify the specific "compounds" alleged to inherently anticipate the instant claims. Applicant therefore respectfully submits that the claims are improperly rejected over Miranda.

The Office Action argues that "[i]t is not necessar[y] that the prior art describe each and every property that a compound may have." Office Action at page 8. However, the differences between Miranda and the claimed invention are not merely ones of terminology. Miranda fails to disclose a system comprising a "high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit," as claimed. Miranda discloses compositions which may include acrylic-based polymers such as Duro-Tak 80-1194, Duro-Tak 80-1196, and Duro-Tak 80-1197. However, none of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21, or greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit as set forth in claims 1-18.

In fact, as shown by the attached data sheets, both Duro-Tak 80-1194 and Duro-Tak 80-1196 have a shear resistance of only 15 hours at 8 pounds per square inch and 72° Fahrenheit, and Duro-Tak 80-1197 has a shear resistance of >24 hours at 4 pounds per square inch and 72° Fahrenheit. *See* Duro-Tak 87-2194 Data Sheet (for Duro-Tak 80-1194, since renamed 87-2194); Duro-Tak 87-2196 Data Sheet (for Duro-Tak 80-1196, since renamed 87-2196); and Duro-Tak 80-1057 Data Sheet (for Duro-Tak 80-1197, now discontinued but in the same family as Duro-Tak 80-1057) (copies attached). Thus, the acrylic-based polymers listed in Miranda do not inherently anticipate the polymers recited in the pending claims.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

B. EP 0 524 776 to Pfister *et al.*

Claims 1-5, 7, 8, 10, 12, and 14-22 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by EP 0 524 776 A1 to Pfister *et al* ("Pfister"). According to the Office Action, Pfister describes "[a] blend of polymers are used in the invention [of Pfister] like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+), nicotine-based drug, and co-solvent excipients (page 2, lines 13+)." Office Action at page 5. Also according to the Office Action, regarding the claimed "shear resistance" property, "[b]ecause the same compounds have the same properties, the limitations which recite "pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit." [i]s an inherent property to the same compounds of the preparation disclosed by Miranda" Office Action at page 6. Applicant respectfully traverses this rejection.

As explained in the previous response, Pfister does not anticipate the invention because, for example, it does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer and (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug that is liquid at or about room temperatures, as set forth in the instant claims. Instead, Pfister generally relates to silicone-based pressure-sensitive adhesive polymer compositions. *See e.g.*, Pfister at page 7, lines 33-57.

The instant claims are distinguished over Pfister because, for example, Pfister does not disclose a high shear resistance "acrylic-based pressure-sensitive adhesive polymer," as claimed. While Pfister mentions the use of a "carbomer" in its silicone-based pressure sensitive adhesive, the "carbomer" is not a "high shear resistant acrylic-based pressure sensitive adhesive polymer," as recited in claim 1. *See* Pfister at page 5, line 25-28. Instead,

the carbomer is used as a "cohesive strengthening agent" (*e.g.*, a filler) and is dispersed in the silicone pressure-sensitive adhesive to increase cohesive strength. *See* Pfister, page 5, lines 29-30. Thus the carbomer is not a "acrylic-based pressure-sensitive adhesive polymer," as claimed. In fact, it is the silicone polymer that is the adhesive in the Pfister composition, while the carbomer is present only as a "cohesive strengthening agent."

The Office Action further argues that "Table C2" allegedly provides evidence of inherency of the recited shear resistance because the values in Table C2 are allegedly "within the range of the instant claims." Office Action, page 13. However, this is a misrepresentation of Table C2. Page 14 of Pfister describes the shear of the entire adhesive composition, which includes the silicone pressure sensitive adhesive and carbomer filler. Pfister does not describe the shear resistance of the individual polymers, let alone that of the acrylic carbomer. Accordingly, Pfister does not teach an acrylic-based pressure-sensitive adhesive polymer with a shear resistance of 50 hours at 8 pounds per square inch at 72° Fahrenheit or 50 hours at 4 pounds per square inch at 72° Fahrenheit, as claimed.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

V. Claim Rejections – 35 U.S.C. § 103

Claims 1-23 stand rejected under 35 U.S.C. § 103 as allegedly anticipated by Pfister in view of U.S. Patent No. 5,284,660 to Lee *et al* ("Lee") and further in view of U.S. Patent No. 5,230,898 to Horstman *et al* ("Horstman"). Office Action, pages 7-8. In making this rejection, the Office Action cites Pfister as the primary reference, cites Lee for teaching a transdermal composition wherein the amount of the drug is 40% of the composition, and cites Horstman for teaching amphetamine. *Id.* Applicant traverses this rejection.

As discussed above, Pfister does not teach or suggest the invention recited in the independent claims. Because neither Lee nor Horstman remedy this deficiency, the combination of Pfister and with Lee and Horstman does not render the claimed invention obvious. Accordingly, this rejection is improper and should be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 18, 2008

By _____

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PRESSURE SENSITIVE & LAMINATING ADHESIVES

DURO-TAK® 87-2194

Description: Duro-Tak 87-2194 is a moderate molecular weight, self-crosslinking, acrylic copolymer pressure sensitive adhesive supplied in an organic solvent solution.

Typical Application: Transdermal drug delivery systems

Typical Physical Properties*:

Appearance:	Solution is clear, colorless to slightly yellow Dry film is clear, colorless		
Total Solids		45	%
Brookfield Viscosity (72°F, 20 rpm, #4)		3000	cps
Solvent System:	Heptane	46	% by weight
	Xylene	21	
	Ethylacetate	15	
	Isopropanol	10	
	Toluene	7	
	2,4-Pentanedione	2	
Density		7.6	lbs/gal
Solubility Parameters (Calculated by group contribution method)			
	Polymer	16	$J^{1/2}/cm^{3/2}$
	Solvent system	17	
Tg (Theoretical glass transition temperature)		-50	°C
Water Vapor Transmission		270	g/m^2/24 hours

Typical Performance Properties*:

180° Peel Adhesion:	20 minutes bond time	55	oz/in width
	24 hours bond time	64	
	1 week bond time	75	
Shear (Holding power: 8 psi @ 72°F)		15	hours
Tack (Loop)		17	oz/in^2

Test strips: 1-mil of dry adhesive backed by a 2-mil polyester film
Test panels: stainless steel

* *All numerical values given are intended for use as guidelines only and do not reflect product specifications.*

Rev. 19-Aug-1996

FDA Drug Master File Status

Detailed information on this product is contained in FDA DMF #4571. The FDA will review this information for you upon receipt of an authorization letter from National. Please contact your technical service representative.

FDA Food Contact Status

The dry film components of Duro-Tak 87-2194 comply with the compositional requirements of the FDA Indirect Food Additive Regulation, 21 CFR 175.105 "Adhesives", 21 CFR 176.180* "Components of paper and paperboard in contact with dry food", and 21 CFR 176.170* (paragraph b) "Components of paper and paperboard in contact with aqueous or fatty food".

*subject to the extractive limitations of the regulation.

Safety Testing

As an indication of the suitability of these products for skin-contact use, National provides results from the following safety testing:

- Cytotoxicity, USP MEM Elution
- USP Biological Class VI (Plastics)
- Primary Dermal Irritancy in Rabbits
- Buehler Sensitization.

The primary dermal irritation score on Duro-Tak 87-2194 is 0.17 which is classified as "minimally-irritating". Please contact your technical service representative for more information.

Drug/Enhancer Compatibility

Compatibility with your formulating ingredients is a function of both the chemical composition and viscoelastic properties of the polymer. Please contact your technical service representative to discuss your particular application.

Product Consistency

Duro-Tak 87-2194 is produced using a computer-controlled manufacturing process in an ISO-9002 certified facility (certified by Underwriters Laboratories Inc., file no. A2910, vol. 1 issued 19-July-1994).

Application Guide

Apply by any conventional method including reverse roll and knife-over-roll. Duro-Tak 87-2194 is designed to be ready for use. If dilution is required, however, ethyl acetate (urethane grade) is suggested.

Typical adhesive deposition is 1 to 2 mils dry for most applications. Drying in a zoned oven is recommended with the last zone as hot as possible to maximize the rate of cure. Cure is dependent upon drying conditions (heat, dwell time).

Storage and Handling

Duro-Tak 87-2194 is stable for a minimum of 12 months from date of manufacture in unopened containers under normal conditions. Between 12 and 24 months from date of manufacture, the material may still be suitable for use if the integrity of the container is intact and the solids and viscosity are within specification. Store drums in dry areas and keep them tightly covered to prevent solvent loss and contamination.

Rotate stock using the oldest material first. Mix the adhesive thoroughly before use and do not mix it with any other products. Consult the Material Safety Data Sheet (MSDS) for hazardous ingredients, flammability, disposal, and related handling information.

Precautions

Review the MSDS carefully before use. Duro-Tak 87-2194 contains flammable solvents; eliminate all sources of ignition before use. Use with adequate ventilation; avoid breathing of vapor; minimize skin contact.

Migratory materials in some face stocks and end use substrates, e.g., vinyl films and foams, may affect performance. It is recommended that Duro-Tak 87-2194 be thoroughly tested for a particular application before large scale use is attempted.

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PRESSURE SENSITIVE & LAMINATING ADHESIVES

DURO-TAK® 87-2196

Description: Duro-Tak 87-2196 is a moderate molecular weight, self-crosslinking, acrylic copolymer pressure sensitive adhesive supplied in an organic solvent solution.

Typical Application: Transdermal drug delivery systems

Typical Physical Properties*:

Appearance:	Solution is clear, colorless to slightly yellow Dry film is clear, colorless		
Total Solids		45	%
Brookfield Viscosity (72°F, 20 rpm, #4)		3000	cps
Solvent System:	Isopropanol	45	% by weight
	Heptane	34	
	Ethylacetate	15	
	Toluene	6	
	2,4-Pentanedione	1	
Density		7.3	lbs/gal
Solubility Parameters (Calculated by group contribution method)			
	Polymer	16	$J^{1/2}/cm^{3/2}$
	Solvent system	20	
Tg (Theoretical glass transition temperature)		-50	°C
Water Vapor Transmission		320	$g/m^2/24$ hours

Typical Performance Properties*:

180° Peel Adhesion:	20 minutes bond time	55	oz/in width
	24 hours bond time	64	
	1 week bond time	75	
Shear (Holding power: 8 psi @ 72°F)		15	hours
Tack (Loop)		30	oz/in^2

Test strips: 1-mil of dry adhesive backed by a 2-mil polyester film
Test panels: stainless steel

* *All numerical values given are intended for use as guidelines only and do not reflect product specifications.*

Rev. 19-Sept-1996

Annex 3

National Starch & Chemical
A member of the ICI Group

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DURO-TAK® 80-1057
Family of Products

Description
The DURO-TAK®1057 products are a family of high peel acrylic solution pressure sensitive adhesives designed for high performance clear film applications.

Family Members
80-1057, 80-1093, 80-1106, 80-1197

Typical Applications
- Clear film labels, decals and overlays
- Metal and film nameplates
- Transfer films and two-side coated mounting tapes
- Note: this product has not been assessed for medical applications.

Typical Performance* (1 dry mil)

	Polyester (2 mil)
180° Peel (oz/in)	
20 minutes	60
24 hours	75
1 week	100
Shear (hours)	
4 psi @ 72°F	>24
Tack (oz/sq in)	30

* Not to be used for setting specifications

FDA Status
The dry film components of DURO-TAK®1057 products comply with the compositional requirements of the FDA Indirect Food Additive Regulation, 21 CFR 175.105 "Adhesives", 21 CFR 176.180** "Components of paper and paperboard in contact with dry food", and 21 CFR 176.170** (paragraph b) "Components of paper and paperboard in contact with aqueous or fatty food".

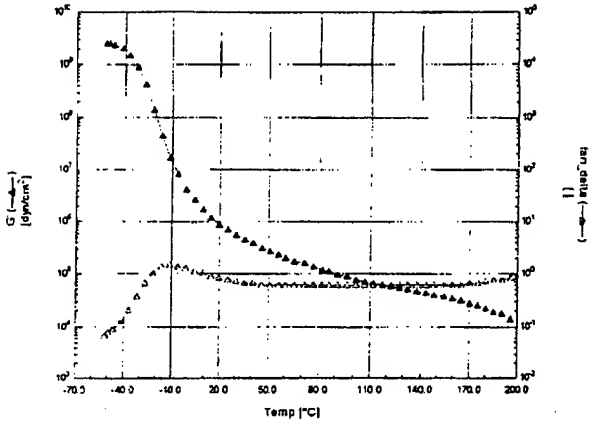
** subject to the extractive limitations of the regulation.

Features
- Self-crosslinking
- High peel and tack
- Excellent clarity; non-yellowing on prolonged exposure to ultraviolet light

Benefits
- One part system
- Excellent adhesion to a variety of substrates
- Suitable for a broad variety of clear film facestocks

Typical Physical Properties*

- Appearance:
  Solution: Clear, colorless to slightly yellow
  Dry Film: Clear, colorless
- Shelf Life: 6 months in unopened containers



Product Number	Solids (%)	Viscosity (cps)	Density (lbs/gal)	Williams Plasticity (mm)	Flash Pt. (°F)	Solvent System (by weight)
80-1057	41	1000	7.2	2.75	<20	40% Isopropanol/36% Heptane/ 12% Ethyl Acetate/8% Xylene/ 4% Toluene
80-1093	53	7000	7.2	2.50	<20	62% Heptane/22% Ethyl Acetate/ 15% Toluene/1% Isopropanol
80-1106	49	3750	7.1	2.50	<20	44% Heptane/38%Ethyl Acetate/ 13%Toluene/3%Vinyl Acetate/1% Isopropanol
80-1197	46	1500	7.0	2.50	<20	43% Isopropanol/ 36% Heptane/ 16% Ethyl Acetate/5% Toluene

* Not to be used for setting specifications

Application Guide

Apply by any conventional method including reverse roll and knife-over-roll. DURO-TAK® 1057 adhesives are designed to be ready for use. If dilution is required, however, ethyl acetate (urethane grade) is suggested.
Typical adhesive deposition is 1 to 2 mils dry for most applications. Drying in a zoned oven is recommended with the last zone as hot as possible to maximize cure rate.

Storage and Handling

The DURO-TAK®1057 product family is stable for a minimum of 6 months under normal conditions. Store drums in dry areas and keep them tightly covered to prevent solvent loss and contamination.

Rotate stock using the oldest material first. Mix the adhesive thoroughly before use and do not mix it with any other products. Consult the Material Safety Data Sheet (MSDS) for hazardous ingredients, flammability, disposal, and related handling information.

Precautions

Review the MSDS carefully before use. DURO-TAK®1057 products contain flammable solvents; eliminate all sources of ignition before use. Use with adequate ventilation; avoid breathing of vapor; minimize skin contact. Migratory materials in some face stocks and end use substrates, e.g., vinyl films and foams, may affect performance. It is recommended that DURO-TAK®1057 products be thoroughly tested for a particular application before large scale use is attempted.